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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NGUYEN, QUANG	
ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
05/27/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/582,241	PARK ET AL.	
	Examiner	Art Unit	
	QUANG NGUYEN, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/9/06;12/5/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3 are pending in the present application, and they are examined on the merits herein.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

The claim is directed to a threonine importer from *Corynebacterium glutamicum*, wherein the threonine importer is expressed by a contiguous DNA sequence from the 1,772 base to the 3,025 base among DNA sequences with the SEQ ID NO. 1. The claim, as written, does not sufficiently distinguish over a threonine importer sequence existing or present in nature from *Corynebacterium glutamicum* because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring product. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claim should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" as taught at least by examples 2-3 of the present specification. See MPEP 2105.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1116.

Applicant's invention is drawn to a threonine-producing *Corynebacterium glutamicum* strain prepared by a method that involves defecting the threonine importer that is expressed by a continuous DNA sequence from the 1,772 base to the 3,025 base of SEQ ID NO.1 in any *Corynebacterium glutamicum*. As written, the instant claims encompass a broad genus of threonine-producing *Corynebacterium glutamicum* strain by simply defecting the threonine importer that is expressed by a continuous DNA

sequence from the 1,772 base to the 3,025 base of SEQ ID NO.1 in any *Corynebacterium glutamicum*.

Apart from disclosing the preparation of a low threonine-requiring *Corynebacterium glutamicum* clone named pECCG-thrY by transforming the high-threonine-requiring *Corynebacterium glutamicum* CJ L-11 CJ with a cloned DNA fragment comprising SEQ ID NO:1 and inactivating the endogenous thrY gene of the threonine-producing *Corynebacterium glutamicum* recombination CJ T-2 strain to generate the CJ T-21 strain that produces a 10% increase of threonine in the culture medium relative to the parent strain, the instant speciation fails to provide sufficient description for **any other *Corynebacterium glutamicum* bacteria that increase the yield of threonine by simply defecting the threonine importer of the present invention**. There is no correlation between a defective ThrY importer and/or *Corynebacterium glutamicum* with the desired activity being claimed, specifically for increasing the yield of threonine. Please note that both the pECCG-ThrY clone and the *Corynebacterium glutamicum* CJ L-11 CJ strain do not produce threonine, but instead they all require exogenous threonine in culture media for growth. Therefore, what are the essential **characteristics or elements possessed by** other threonine-producing *Corynebacterium glutamicum* strains that have a defective threonine importer apart from the disclosed CJ T-21 strain? The instant disclosure also does not reasonably convey to a skilled artisan at the time the invention was made that **Applicant was in possession of a representative number of species for a broad genus of a threonine-producing strain as broadly claimed**. Furthermore, at the effective filing

date of the present application, Palmieri et al (Arch Microbiol. 165:48-54, 1996; IDS) already taught that threonine production can only be observed in *C. glutamicum* mutants or *C. glutamicum* recombinant strains in which threonine biosynthesis is released from feed-back regulation, and not any *C. glutamicum* (see at least page 48, col. 2, last paragraph).

The claimed invention as a whole is not adequately described if the claims require essential or critical elements that are not adequately described in the specification. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot fully envision the detailed structure for a representative number of species for a broad genus of threonine-producing *Corynebacterium glutamicum* strain by simply defecting the threonine importer that is expressed by a continuous DNA sequence from the 1,772 base to the 3,025 base of SEQ ID NO.1 in any *Corynebacterium glutamicum* as broadly claimed, and therefore conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating or characterizing it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Nakagawa et al. (US 2002/0197605).

The claim is drawn to a threonine importer from *Corynebacterium glutamicum*, wherein the threonine importer is expressed by a contiguous DNA sequence from the 1772 base to the 3,025 base among DNA sequences with the SEQ ID NO.1.

Nakagawa et al already disclosed *Corynebacterium glutamicum* SEQ ID NO:1 comprising a threonine importer nucleic acid sequence (nucleotides 3,231,051 to 3,232,304) that is 100% identical to the DNA sequence from the 1,772 base to the 3,025 base of SEQ ID NO:1 of the present invention (see at least Summary of the Invention, paragraph 20 and SEQ ID NO:1).

Please, also note that where, as here, the claimed and prior art products are identical **or** substantially identical, **or** are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not

necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Accordingly, the teachings of Nakagawa et al meet every limitation of the claim as broadly written. Therefore, the reference anticipates the instant claim.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/QUANG NGUYEN, Ph.D./

Primary Examiner, Art Unit 1633